

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Dedrick et al. Serial No.: To be assigned Filed: June 20, 2003 For: Treatment Method	Group Art Unit: To be assigned Examiner: To be assigned <hr/> Express Mail No. EV 351927914 US Mailed June 20, 2003
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INFORMATION DISCLOSURE STATEMENT

Box Patent Applications
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) **and** a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in prior application Serial Nos. 09/527,957 (filed March 17, 2000) and 09/819,921 (filed March 28, 2001), and relied upon in this application for an earlier filing date under 35 USC § 120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: June 20, 2003

By: _____

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PATENT TRADEMARK OFFICE

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1747R1D1C1	Serial No.		
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Dedrick et al.			
				Filing Date 20 Jun 2003	Group		
U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	5,002,869	26.03.91	Schlossman et al.			
	* 2	5,071,964	10.12.91	Dustin et al.			
	* 3	5,622,700	22.04.97	Jardieu et al.			
FOREIGN PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	* 4	8,815,518	10.11.88	AUSTRALIA			
	* 5	2,008,368	13.06.91	CANADA			
	* 6	289,949	11.11.88	EPO			
	* 7	346,078	13.12.89	EPO			
	* 8	379,904	01.08.90	EPO			
	* 9	387,668	19.09.90	EPO			
	*10	WO 88/06592	07.09.88	PCT			
	*11	WO 90/10652	20.09.90	PCT			
	*12	WO 90/15076	13.12.90	PCT			
	*13	WO 91/16927	14.11.91	PCT			
	*14	WO 91/16928	14.11.91	PCT			
	*15	WO 91/18011	28.11.91	PCT			
	*16	WO 94/02175	03.02.94	PCT			
	*17	WO 94/04188	03.03.94	PCT			
	*18	WO 98/23761	04.06.98	PCT			
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)							
	*19	Abramowicz et al., "Release of tumor necrosis factor, interleukin-2, and gamma-interferon in serum after injection of OKT3 monoclonal antibody in kidney transplant recipients" <u>Transplantation</u> 47(4):606-608 (Apr 1989)					
	*20	Azzawi et al., "Identification of Activated T Lymphocytes and Eosinophils in Bronchial Biopsies in Stable Atopic Asthma" <u>Am. Rev. Resp. Dis.</u> 142:1407-1413 (1990)					
	*21	Bauer et al., "Population pharmacokinetics and pharmacodynamics of the anti-CD11a antibody hull24 in human subjects with psoriasis" <u>J. Pharmacokinetics and Biopharmaceutics</u> 27(4):397-420 (1999)					
	*22	Benjamin et al., "Mechanisms of Monoclonal Antibody-Facilitated Tolerance Induction: A Possible Role for the CD4(L3T4) and CD11a (LFA-1) Molecules in Self-Non-Self Discrimination" <u>European Journal of Immunology</u> 18:1079-1088 (1988)					
	*23	Campana et al., "Human leukocyte function-associated antigens on lympho-hemopoietic precursor cells" <u>European Journal of Immunology</u> 16(5):537-542 (May 1986)					
	*24	Cavazzana-Calvo et al., "A phase II trial of partially incompatible bone marrow transplantation for high-risk acute lymphoblastic leukaemia in children: prevention of graft rejection with anti-LFA-1 and anti-CD2 antibodies." <u>British Journal of Haematology</u> 93(1):131-138 (Apr 1996)					
	*25	Cavazzana-Calvo et al., "Prevention of bone marrow and cardiac graft rejection in an H-2 haplotype disparate mouse combination by an anti-LFA-1 antibody" <u>Transplantation</u> 59(11):1576-1582 (Jun 15, 1995)					
	*26	Chatenoud et al., "In vivo cell activation following OKT3 administration. Systemic cytokine release and modulation by corticosteroids" <u>Transplantation</u> 49(4):697-702 (Apr 1990)					
Examiner					Date Considered		
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*27	Chatenoud et al., "Systemic reaction to the anti-T-cell monoclonal antibody OKT3 in relation to serum levels of tumor necrosis factor and interferon- α " <u>New England J. of Medicine</u> 320(21):1420-1421 (May 25, 1989)				
*28	Cockcroft et al., "Prediction of airway responsiveness to allergen from skin sensitivity to allergen and airway responsiveness to histamine" <u>Am. Rev. Respir. Dis.</u> 135:264-267 (1987)				
*29	Collins, T., "Adhesion molecules in leukocyte emigration" <u>Science and Medicine</u> pps. 28-37 (1995)				
*30	Connolly et al., "Treatment of murine lupus with monoclonal antibodies to lymphocyte function-associated antigen-1: dose-dependent inhibition of autoantibody production and blockade of the immune response to therapy" <u>Clinical Immunology & Immunopathology</u> 72(2):198-203 (Aug 1994)				
*31	Corrigan & Kay, "CD4 T-Lymphocyte Activation in Acute Severe Asthma" <u>Am. Rev. Respir. Dis.</u> 141:970-977 (1990)				
*32	Cosimi et al., "Use of monoclonal antibodies to T-cell subsets for immunologic monitoring and treatment in recipients of renal allografts" <u>New England J. of Medicine</u> 305(6):308-314 (Aug 6, 1981)				
*33	Crescioli et al., "Theophylline inhibits early and late asthmatic reactions induced by allergens in asthmatic subjects" <u>Ann. Allergy</u> 66:245-251 (March 1991)				
*34	Curnow, R., "Clinical experience with CD64-directed immunotherapy. An overview" <u>Cancer Immunology and Immunotherapy</u> 45(3-4):210-215 (Nov-Dec 1997)				
*35	Desroches et al., "Regulation and Functional Involvement of Distinct Determinants of Leucocyte Function-Associated Antigen 1 (LFA-1) in T-Cell Activation In Vitro" <u>Scand. J. Immunol.</u> 33:277-286 (1991)				
*36	Djukanovic et al., "Effect of an Inhaled Corticosteroid on Airway Inflammation and Symptoms in Asthma" <u>Am. Rev. Respir. Dis.</u> 145:669-674 (1992)				
*37	Dustin and Springer, "Lymphocyte function-associated antigen-1 (LFA-1) interaction with intercellular adhesion molecule-1 (ICAM-1) is one of at least three mechanisms for lymphocyte adhesion to cultured endothelial cells" <u>Journal of Cell Biology</u> 107(1):321-331 (Jul 1988)				
*38	Dustin and Springer, "Role of lymphocyte adhesion receptors in transient interactions and cell locomotion" <u>Annual Review of Immunology</u> 9:27-66 (1991)				
*39	Dustin et al., "Induction By IL 1 and Interferon- γ : Tissue Distribution, Biochemistry, and Function of a Natural Adherence Molecule (ICAM-1)" <u>The Journal of Immunology</u> 137(1):245-254 (July 1, 1986)				
*40	Fekete et al., "Involvement of Lymphocyte Function-Associated Antigen-1 (LFA-1) But Not ICAM-1 in a Radioactive Leukocyte Cell-Mediated Immunity (LA-CMI) Assay" <u>J. Clin. Lab. Immunol.</u> 31:145-149 (1990)				
*41	First et al., "The effect of indomethacin on the febrile response following OKT3 therapy" <u>Transplantation</u> 53(1):91-94 (Jan 1992)				
*42	Fischer et al., "Reduction of Graft Failure by a Monoclonal Antibody (Anti-LFA-1 CD11a) After HLA Nonidentical Bone Marrow Transplantation in Children with Immunodeficiencies, Osteopetrosis, and Fanconi's Anemia" <u>Blood</u> 77(2):249-256 (January 15, 1991)				
*43	Fischer et al., "Role of the LFA-1 Molecule in Cellular Interactions Required For Antibody Production in Humans" <u>The Journal of Immunology</u> 136(9):3198-3203 (May 1, 1986)				
*44	Goldman et al., "OKT3-induced cytokine release attenuation by high-dose methylprednisolone" <u>Lancet</u> 2(8666):802-803 (Sep 30, 1989)				
*45	Goldstein et al., "A randomized clinical trial of OKT3 monoclonal antibody for acute rejection of cadaveric renal transplants. Ortho Multicenter Transplant Study Group" <u>New England J. of Medicine</u> 313(6):337-342 (Aug 8, 1985)				
*46	Gordon et al., "Both anti-CD11a (LFA-1) and anti-CD11b (MAC-1) therapy delay the onset and diminish the severity of experimental autoimmune encephalomyelitis" <u>Journal of Neuroimmunology</u> 62(2):153-160 (Nov 1995)				
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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
	*47	Gottlieb et al., "Psoriasis is clinically and histologically improved by treatment with a humanized anti-CD11a monoclonal antibody (hu1124): results of a multicenter, multiple ascending dose study" <u>J. Investigative Dermatology</u> (abstract only) 112(4):647 (April 1999)			
	*48	He et al., "Effect of LFA-1 and ICAM-1 antibody treatment on murine corneal allograft survival" <u>Invest. Ophthalmol. Vis. Sci.</u> 35:3218-3225 (1994)			
	*49	Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" <u>European Journal of Immunology</u> 13:202-208 (1983)			
	*50	Hourmant et al., "A randomized multicenter trial comparing leukocyte function-associated antigen-1 monoclonal antibody with rabbit antithymocyte globulin as induction treatment in first kidney transplantations" <u>Transplantation</u> 62(11):1565-1570 (Dec 15, 1996)			
	*51	Hourmant et al., "Administration of an Anti-CD11a Monoclonal Antibody in Recipients of Kidney Transplantation" <u>Transplantation</u> 58(3):377-380 (August 1994)			
	*52	Isaacs et al., "Humanized anti-CD4 monoclonal antibody therapy of autoimmune and inflammatory disease" <u>Clinical & Experimental Immunology</u> 110(2):158-166 (Nov 1997)			
	*53	Isobe et al., "Specific acceptance of cardiac allograft after treatment with antibodies to ICAM-1 and LFA-1" <u>Science</u> 255(5048):1125-1127 (Feb 28, 1992)			
	*54	Kato et al., "Specific acceptance of fetal bowel allograft in mice after combined treatment with anti-intercellular adhesion molecule-1 and leukocyte function-associated antigen-1 antibodies" <u>Annals of Surgery</u> 223(1):94-100 (Jan 1996)			
	*55	Krensky et al., "The Functional Significance, Distribution, and Structure of LFA-1, LFA-2, and LFA-3: Cell Surface Antigens Associated with CTL-Target Interactions" <u>The Journal of Immunology</u> 131(2):611-616 (August 1983)			
	*56	Kuypers and Roos, "Leukocyte Membrane Adhesion Proteins LFA-1, CR3 and p150,95: A Review of Functional and Regulatory Aspects" <u>Res. Immunol.</u> 140:461-486 (1989)			
	*57	Le Mauff et al., "Effect of anti-LFA1 (CD11a) monoclonal antibodies in acute rejection in human kidney transplantation" <u>Transplantation</u> 52(2):291-296 (Aug 1991)			
	*58	Nakakura et al., "Potent and Effective Prolongation by Anti-LFA-1 Monoclonal Antibody Monotherapy of Non-Primarily Vascularized Heart Allograft Survival in Mice Without T Cell Depletion" <u>Transplantation</u> 55(2):412-417 (February 1993)			
	*59	Nishihara et al., "Potent immunosuppressive effect of anti-LFA-1 monoclonal antibody on islet allograft rejection" <u>Transplantation Proc.</u> 27:372 (1995)			
	*60	Nishimura et al., "Lymphokine-activated cell-associated antigen involved in broad-reactive killer cell-mediated cytotoxicity" <u>Cellular Immunology</u> 94(1):122-132 (Aug 1985)			
	*61	Nishimura et al., "The role of lymphokine-activated cell-associated antigen. III. Inhibition of T-cell activation by monoclonal killer-blocking antibody" <u>Cellular Immunology</u> 107(1):32-39 (Jun 1987)			
	*62	Raasveld et al., "Complement activation during OKT3 treatment: a possible explanation for respiratory side effects" <u>Kidney International</u> 43(5):1140-1149 (May 1993)			
	*63	Sanchez-Madrid et al., "Mapping of antigenic and functional epitopes on the α - and β -subunits of two related mouse glycoproteins involved in cell interactions, LFA-1 and MAC-1" <u>Journal of Experimental Medicine</u> 158(2):586-602 (Aug 1, 1983)			
	*64	Springer et al., "The lymphocyte function-associated LFA-1, CD2, and LFA-3 molecules: cell adhesion receptors of the immune system" <u>Annual Review of Immunology</u> 5:223-252 (1987)			
	*65	Stoppa et al., "Anti-LFA1 Monoclonal Antibody (25.3) for Treatment of Steroid-resistant Grade III-IV Acute Graft-versus-host Disease" <u>Transplant International</u> 4:3-7 (1991)			
	*66	Talento et al., "A single administration of LFA-1 antibody confers prolonged allograft survival" <u>Transplantation</u> 55:418-422 (1993)			
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	*67	Tanaka et al., "Prolonged inhibition of an antigen-specific IgE response in vivo by monoclonal antibody against lymphocyte function-associated antigen-1" <u>European Journal of Immunology</u> 25:1555-1558 (1995)			
	*68	Taylor et al., "The expression of CD18 is increased on Trisomy 21 (Down syndrome) lymphoblastoid cells" <u>Clinical & Experimental Immunology</u> 71(2):324-328 (Feb 1988)			
	*69	Van Dijken et al., "Evidence That Anti-LFA-1 in vivo Improves Engraftment and Survival After Allogeneic Bone Marrow Transplantation" <u>Transplantation</u> 49(5):882-886 (May 1990)			
	*70	Vasconcellos et al., "Cytotoxic Lymphocyte Gene Expression in Peripheral Blood Leukocytes Correlates with Rejecting Renal Allografts" <u>Transplantation</u> 66:562-566 (1998)			
	*71	Walker et al., "T Cell Subsets and Their Soluble Products Regulate Eosinophilia in Allergic and Nonallergic Asthma" <u>J. Immunol.</u> 146(6):1829-1935 (March 15, 1991)			
	*72	Ward et al., "Blocking of Adhesion Molecules in vivo as Anti-Inflammatory Therapy" <u>Therapeutic Immunology</u> 1:165-171 (1994)			
	*73	Ward et al., "Theophylline--an Immunomodulatory Role In Asthma?" <u>Am. Rev. Respir. Dis.</u> 147(3):518-523 (1993)			
	*74	Werther et al., "Humanization of an Anti-Lymphocyte Function-Associated Antigen (LFA)-1 Monoclonal Antibody and Reengineering of the Humanized Antibody for Binding to Rhesus LFA-1" <u>J. of Immunology</u> 157:4986-4995 (1996)			
	*75	Woodle et al., "OKT3 escalating dose regimens provide effective therapy for renal allograft rejection" <u>Clinical Transplantation</u> 10(4):389-395 (Aug 1996)			
	*76	de Fougères et al., "Characterization of the function of intercellular adhesion molecule (ICAM)-3 and comparison with ICAM-1 and ICAM-2 in immune responses" <u>Journal of Experimental Medicine</u> 179(2):619-629 (Feb 1, 1994)			
	*77	ten Berge et al., "Consequences of OKT3 administration via continuous infusion as compared to bolus infusion" <u>Transplantation Proceedings</u> 28(6):3217-3220 (Dec 1996)			
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